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In situ comparison of varying composite tibial tunnel interference screws used for ACL soft tissue graft fixation

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ABSTRACT

Purpose: This mechanical study using an in vitro porcine model compared composite interference screw fixation of soft tissue ACL grafts in tibial tunnels.
Methods: Forty-eight porcine profundus tendons and tibiae were divided into four groups of 12 closely matched specimens. Equivalent diameter grafts were assigned to each group. Tibial bone tunnels were drilled to 0.5 mm greater than graft diameter. Grafts were fixed in tunnels using one 10 × 35 mm composite interference screw designed by four different manufacturers. Maximal insertion torque and perceived within group mechanical testing outcome predictions were recorded. Constructs were potted and loaded into a six degrees of freedom clamp that placed the servohydraulic device tensile loading vector in direct tunnel alignment. Constructs were pre-loaded to 25 N, pre-conditioned between 0 and 50 N for 10 cycles (0.5 Hz), submaximally tested between 50 and 250 N for 500 cycles (one hertz) and load to failure tested at 20 mm/min.
Results: Statistically significant differences were not observed between groups for displacement during submaximal cyclic loading, yield load, displacement at yield load, stiffness, ultimate load at failure and displacement at ultimate load. One composite screw group displayed a slightly greater proportion of specimens that required use of more than one screw during insertion.
Conclusions: Under highly controlled conditions groups displayed comparable fixation.

1. Introduction

The gold standard interference screw would be non-metallic, easy to use, and able to provide strong fixation until the graft incorporates, and then undergoes full resorption being replaced by bone [1]. Degradation kinetics differ substantially among different bioabsorbable polymers and numerous factors affect degradation rates, including molecular weight, sterilization, implant size, self-reinforcement, copolymer or stereocopolymer ratios, and processing techniques [2]. Postoperative radiographic evaluation of early generation poly-L-lactic acid (PLLA), polyglycolide and poly-D,L-lactide-co-glycolide screws revealed slow resorption rates and minimal, if any, osteoconductivity, despite good to excellent clinical results [3–11]. The addition of β-tricalcium phosphate (βTP) or hydroxyapatite (HA) helps buffer PLLA acidic breakdown providing a scaffold for bony ingrowth [12,13]. The addition of βTP or HA, can accelerate the incorporation of tendon grafts into bone tunnels and provide better mechanical properties [12–15]. Use of composite interference screws may lead to earlier and stronger graft incorporation, replacement of the screws with cancellous bone, and easier revision surgery. When ease of use and initial soft tissue graft fixation is comparable, composite screw selection should be based more on tissue remodeling and osteoconductive properties during resorption and the completeness of resorption. The purpose of this mechanical study using an in vitro porcine model was to compare composite interference screw fixation of soft tissue ACL grafts in tibial tunnels. Under strict controls the following 10 × 35 mm composite interference screw groups were compared: (Group 1) DePuy Milagro, (Group 2) Arthrex BioComposite, (Group 3) Stryker Biosteon, and (Group 4) Smith & Nephew Biosure HA (Fig. 1). The study hypothesis was that significant group differences would not exist.

2. Methods

An a priori power analysis based on pilot testing revealed that a minimum of 10 specimens/group were needed to attain a statistical power of 0.80 at an alpha level of $P = 0.05$. To accommodate for possible methodological difficulties 12 specimens per study group were used. Forty-eight porcine profundus tendons and tibiae were divided into four groups of 12 closely matched specimens. From a group of 100 tibiae, pre-screening for bone mineral density (BMD) was performed using anterior–posterior and mediolateral dual-energy X-ray absorptiometry (DXA) (QDR 4500, Hologic, Inc., Bedford, MA, USA) scans to only

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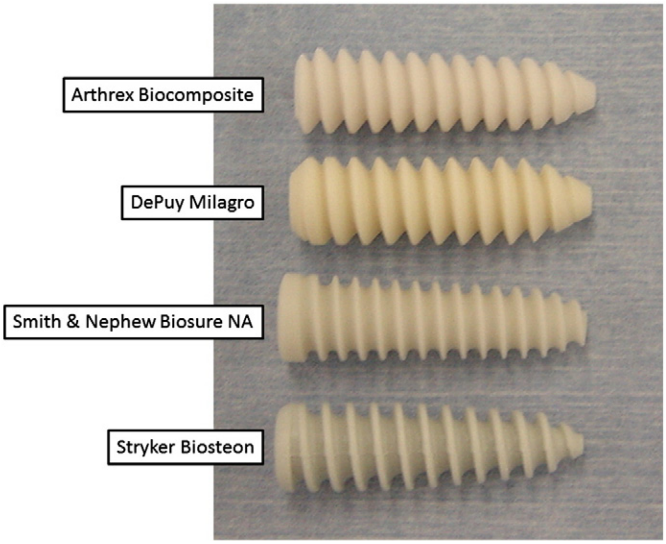

Fig. 1. Composite 10 × 35 mm interference screw comparison (top-to-bottom): Arthrex Biocomposite, DePuy Milagro, Smith & Nephew Biosure HA, and Stryker Biosteon.

select specimens that simulated human tibial bone mineral density (approximately 1.09–1.30 g/cm^2). Tibiae with comparable BMD were randomly assigned to a composite interference screw group. Equivalent diameter whip-stitched soft tissue tendon grafts were prepared using manufacturer recommended suture material: (Group 1) DePuy Mitek Orthocord, (Group 2) Arthrex FiberWire, (Group 3) Stryker Force Fiber, and (Group 4) Smith Nephew UltraBraid and were also assigned to their respective group.

After identification of the tibial ACL footprint, using a drill guide fixed to the footprint, a guide wire was inserted at 55° from the tibial plateau through the native ACL insertion. Tibial tunnels 0.5 mm greater than graft diameter were then drilled. Grafts were fixed in tunnels using one of four different 10 × 35 mm composite interference screws: (Group 1) DePuy Milagro consisting of 30% βTP and 70% poly-L-lactide-co-glycolide, (Group 2) Arthrex BioComposite consisting of 30% biphasic calcium phosphate and 70% poly-D-lactide, (Group 3) Stryker Biosteon consisting of 25% HA and 75% PLLA, or (Group 4) Smith & Nephew Biosure HA consisting of 25% HA and 75% PLLA [14]. The same fellowship trained surgeon (RK) performed all graft implantations and composite interference screw insertions. Maximal insertion torque (AccuForce Torque-chek, Ametek, Largo, FL) and perceived within group mechanical testing outcome predictions (0 to 10 visual analog scale, end range descriptors 0 = extremely poor, 10 = excellent) were recorded.

Following preparation, constructs were potted in 7.62 cm (three inches) diameter, 17.78 cm (seven inches) long PVC tubes and loaded into a six degrees of freedom clamp. The specially designed clamp enabled the servohydraulic device (MTS 858, Eden Prairie, MN) tensile loading vector to be aligned directly with the tunnel (Fig. 2) [16–18]. This direct tensile load on the looped soft tissue tendon graft provided a “worst case” loading scenario. Constructs were pre-loaded to 25 N, followed by a pre-conditioning phase (0 to 50 N, 0.5 Hz, 10 cycles). After pre-conditioning, constructs underwent 500 submaximal loading cycles between 50 and 250 N at one hertz. Lastly, the constructs underwent load to failure testing at 20 mm/min with load (N) and displacement (mm) data recorded at 10 Hz. Groups were compared for independent variables of displacement during submaximal cyclic loading, yield load, ultimate load, stiffness, and displacement during ultimate load testing. Groups were also compared for the frequency of needing more than one composite interference screw to achieve fixation. Yield load represented the point in the stress–strain curve where a non-linear relationship was observed. Stiffness was determined by recording peak load along the linear portion of the stress–strain curve, subtracting this from the minimum load, and dividing this value by the construct displacement difference between the points. Ultimate load represented the maximum load observed prior to construct failure.

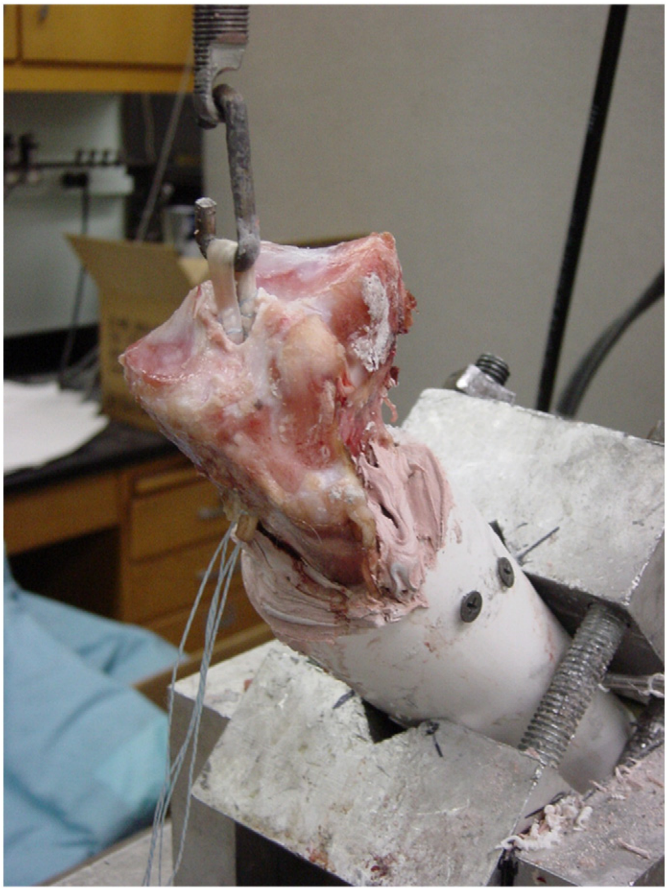

Fig. 2. ACL graft–tibia construct mechanical testing in servohydraulic device using custom clamp.

3. Statistical analysis

Kolmogorov–Smirnov tests revealed that data displayed a normal distribution for yield and ultimate load at failure and for displacement at yield and ultimate failure loads; therefore parametric statistical analysis was performed. Normality was determined for both the complete dataset and for only those constructs that scored at least satisfactory for the perceived mechanical test outcome prediction. A series of one-way ANOVA were used to confirm that groups displayed comparable construct preparation characteristics and to evaluate group mechanical test differences. A Fisher's Exact Test was used to determine frequency between groups for the number of specimens that required more than one screw due to breakage. An alpha level of $P < 0.05$ was used to indicate statistical significance. All statistical procedures were performed using SPSS version 21.0 software (IBM Corporation, Armonk, NY).

4. Results

Groups displayed comparable tibial BMD, graft diameter, graft length, composite interference screw insertion torque, perceived mechanical test outcome prediction, graft loop distance, and tibial tunnel length (Table 1). Group 3 had more specimens that required more than one screw (4/12 specimens, 33.3%) because of insertion breakage (Fisher's Exact Test = 6.9, $P = 0.043$). Statistically significant differences were not observed between groups for displacement during submaximal cyclic loading, yield load, displacement at yield load, stiffness, ultimate load at failure, and displacement at ultimate load (Table 2).